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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0418; FRL-9925-78]

Phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends an exemption from the requirement of a tolerance for residues of phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- (CAS Reg. No. 23328-53-2) to allow its use on all growing crops as an inert ingredient (ultraviolet (UV) stabilizer) at a maximum concentration of 10% in pesticide formulations, Loveland Products Inc., submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act (FFDCA). This regulation eliminates the need to establish a maximum permissible level for residues of phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-.

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0418, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0418 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business

Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0418, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Background and Statutory Findings

In the **Federal Register** of September 5, 2014 (79 FR 53009) (FRL-9914-98), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP IN-10704) by Loveland Products, Inc., 3005 Rocky Mountain Avenue, Loveland, CO 80538. The petition requested that the exemption from the requirement of a tolerance in 40 CFR 180.920 for residues of phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl be amended to allow for use on all growing agricultural crops when used as an inert ingredient (UV stabilizer) at a maximum concentration of 10% weight/weight in pesticide formulations. That document referenced a summary of the petition prepared by the petitioner Loveland Products, Inc., which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant

information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

In the **Federal Register** of August 18, 2010 (75 FR 50884) (FRL-8836-3), EPA published a final rule establishing an exemption from the requirement of tolerances for residues of phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- when used as an inert ingredient (UV stabilizer) at a maximum concentration of 0.6% in insecticide formulations applied to adzuki beans, canola, chickpeas, cotton, fava beans, field peas, lentils, linola, linseed, lucerne, lupins, mung beans, navy beans, pigeon peas, safflower, sunflower, and vetch. Specific information on the studies received and the nature of the adverse effects caused by phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- as well as the NOAEL and the LOAEL from the toxicity studies are discussed in that rulemaking which can be found in the docket under docket ID numbers EPA-HQ-OPP-2008-0602.

Since that rulemaking, as part of the data submitted in support of the current petition, an additional study has been submitted. In this study, a one-generation oral reproduction study (OECD Test Guideline 443) with the rat, the NOAEL for phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- for parental and reproductive toxicity was 10,000 parts per million (ppm) (equal to 618 milligram/kilogram/day (mg/kg/day), the highest dose tested (HDT)). The NOAEL for offspring toxicity was 5,000 ppm (equal to 311 mg/kg/day) based on decreased body weight, body weight gain, increased absolute spleen weights in males and increased incidence of splenic extra medullary hematopoiesis in males at the LOAEL of 10,000 ppm (equal to 618 mg/kg/day). Specific information on the study received and the nature of the adverse effects caused by phenol-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, as well as the NOAEL and LOAEL can found at *http://www.regulations.gov* in the document “Phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- ; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Amendment to the Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Preharvest Pesticide Products” at pp. 16-19 in docket ID number EPA-HQ-OPP-2014-0418. Based on the results of this study, the NOAEL for parental and reproductive toxicity was 10,000 ppm (equal to 618 mg/kg/day, the HDT). The NOAEL for offspring toxicity was 5,000

ppm (equal to 311 mg/kg/day) based on the decreased body weight, body weight gain, increased absolute spleen weights in males and increased incidence of splenic extra medullary hematopoiesis in males at 10,000 ppm (equal to 618 mg/kg/day).

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide chemical's toxicological profile is determined. EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

No acute effects were observed from a single dose so no acute POD was selected. The POD for risk assessment for all remaining durations and routes of exposure was from the 90-day toxicity study in rats. The NOAEL was 20 mg/kg/day and the LOAEL was 40 mg/kg/day based on increases in liver, kidney, spleen, and testes weights. Although the chronic point of departure was selected from a subchronic study, no additional uncertainty factor is necessary for use of subchronic study for chronic exposure assessment since available longer-term studies shows the lack of toxicity even at higher doses. A 100-fold uncertainty factor was used for the chronic exposure (10X interspecies extrapolation, 10X for intraspecies variability and 1X Food Quality Protection Act (FQPA) factor. The NOAEL of 20 mg/kg/day was used for all exposure duration via dermal and inhalation routes of exposure. The residential, occupational and aggregate level of concern (LOC) is for MOEs that are less than 100 and is based on 10X interspecies extrapolation, 10X for intraspecies variability and 1X FQPA factor. Dermal absorption is estimated to be 10% based on SAR analysis. A 100% inhalation absorption is assumed.

In the **Federal Register** of August 18, 2010 (75 FR 50884) (FRL-8836-3), EPA applied 10X FQPA factor for the lack of a reproduction study; however, the recently submitted Extended One-Generation Reproduction Toxicity Study of Tinuvin 571 in Wistar Rats provides a reliable basis for reducing the FQPA factor used in the previous risk assessment to 1X.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from phenol,

2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- in food as follows: Because no acute endpoint was identified, no acute dietary exposure assessment was conducted.

In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model/Food Commodity Intake Database (DEEM-FCID)^{TM}, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, no residue data were submitted for phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-. In the absence of specific residue data, EPA has developed an approach that uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts" (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA-HQ-OPP-2008-0738.

In the case of phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, EPA made a specific adjustment to the dietary exposure assessment to account for the use limitations of the amount of phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- that may be in formulations (no more than 10% by weight in pesticide products applied to growing crops) and assumed that phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- is present at the maximum limitation in all pesticide product formulations used on growing crops.

2. *Dietary exposure from drinking water*. For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Residential uses of pesticides containing phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- are extremely limited. However, in order to account for all of the current and unanticipated potential residential uses of pesticide products containing phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- various exposure models were employed. The Agency believes that the scenarios assessed represent highly conservative worst-case short-term and intermediate-term exposures and risks to residential handlers and those experiencing post-application exposure resulting from the use of indoor and outdoor pesticide products containing this inert ingredient in residential environments. Based on the use pattern, chronic exposure is not anticipated. Therefore, the risk from the chronic residential exposure was not assessed.

Further details of this residential exposure and risk analysis can be found at *http://www.regulations.gov* in the memorandum entitled "JITF Inert Ingredients. Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations" (D364751, Lloyd/LaMay, 5/7/09) in docket ID number EPA-HQ-OPP-2008-0710.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, to share a common mechanism of toxicity with any other substances, and phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Developmental studies have been conducted on two structurally similar chemicals. In one study, no maternal toxicity was evident and the rates of implantation and embryo toxicity were not affected by treatment in rats. No teratogenic effects were observed; however, the study does not specify what developmental endpoints were examined. The NOAEL for maternal and developmental toxicity was 1,000 mg/kg/day (HDT). In a separate study, there was no evidence of increased susceptibility in this developmental toxicity study in rats and mice at 1,000 mg/kg/day. In a second study in rats, no maternal toxicity was observed at any dose tested. The maternal toxicity NOAEL was 3,000 mg/kg/day. The developmental NOAEL was 1,000 mg/kg/day based on omphalocele seen in the one fetus in the high dose group (LOAEL 3,000 mg/kg/day). The data suggest evidence of

increased susceptibility in this developmental toxicity study in rats. However, there is a low concern for this susceptibility because the adverse effect (omphalocele) was seen at a very high dose of 3,000 mg/kg/day and only in one fetus. In addition, the study did not provide historical controls that would assist in making a determination as to whether this effect is treatment related.

No adverse reproductive effects were observed in a one-generation reproductive toxicity study in rats at dose levels up to 10,000 ppm; equal to 618 mg/kg/day, the HDT. There is a quantitative evidence of increased susceptibility in the one-generation reproduction study in rats. In this study, the NOAEL for offspring toxicity was 5,000 ppm (equal to 311 mg/kg/day) based on decreased body weight, body weight gain, increased absolute spleen weights in males and increased incidence of splenic extra medullary hematopoiesis in males at the LOAEL of 10,000 ppm (equal to 618 mg/kg/day), while no systemic toxicity was observed in parental animals at doses up to 10,000 ppm (equal to 618 mg/kg/day). However, the concern for this susceptibility is low since there is a well characterized NOAEL for protecting the offspring and the NOAEL selected for chronic RfD is more than 12 fold lower. Therefore, there is no need for additional uncertainty factor.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, is complete. Previously (2010), EPA identified study measuring reproductive parameters and lack of Immunotoxicity study as the data gaps. Since the last assessment, EPA received the one generation reproduction study. EPA concluded that the Immunotoxicity study is not required because the newly submitted study and previously reviewed studies do not show any indication of Immunotoxicity except one 90-day toxicity study in rats showing slight increases in spleen weights without histopathological findings and without changes in the blood parameters was observed at the HDT (80 mg/kg/day). Since this is an isolated finding, EPA concluded that the Immunotoxicity study is not required.

ii. There is no indication that phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity. No clinical signs of neurotoxicity were seen in any of the repeat dose studies with phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-.

iii. No evidence of Immunotoxicity was seen in the available database except in one 90-day toxicity study in rats showing slight increases in spleen weights without histopathological findings and without changes in the blood parameters was observed at the HDT (80 mg/kg/day). Since this is isolated findings, EPA concluded that the Immunotoxicity study is not required.

iv. There is qualitative evidence of post natal susceptibility in 1-generation reproduction study in rats, however, EPA concluded that there is no need for additional uncertainty factor since there is well characterized NOAEL protecting the offspring and the NOAEL selected for chronic RfD is more than 12 fold lower.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed using highly conservative model assumptions including 100 percent crop treated (PCT) and residue levels in crops equivalent to the highest established active ingredient tolerance. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-.

E. Aggregate Risks and Determination of Safety

Determination of safety section. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk. A*n acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- from food and water will utilize 70.6% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure: Based on the explanation in this unit, regarding residential use patterns, chronic residential exposure to residues of phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl -, is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, is currently used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic

exposure through food and water with short-term residential exposures to phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-,.

Using the exposure assumptions described in this unit for short-term exposures and the use limitation described previously in Unit C. EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 170 for adult males and females. Adult residential exposure combines high-end dermal and inhalation handler exposure from liquids/trigger sprayer in home gardens with a high-end post-application dermal exposure from contact with treated lawns. EPA has concluded the combined short-term aggregated food, water, and residential exposures result in an aggregate MOE of 140 for children. Children's residential exposure includes total exposures associated with contact with treated lawns (dermal and hand-to mouth exposures). The EPA's level of concern for phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- is for MOEs that are lower than 100; therefore, these MOEs are not of concern.

4. *Intermediate-term risk*. Phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, is currently used as an inert ingredient in pesticide products that are registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-.

Intermediate-term aggregate risk assessment was not conducted because short-term aggregate risk assessment is protective of intermediate-term aggregate risk since the same endpoint of concern has been identified for both exposure durations.

5. *Aggregate cancer risk for U.S. population.* Phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- is not expected to pose a cancer risk to humans since there was no evidence of carcinogenicity in the available studies.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- in or on any food commodities. EPA is establishing a limitation on the amount of phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, that may be used in pesticide formulations. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. EPA will not register any

pesticide for sale or distribution that contains greater than 10% of phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, by weight in the pesticide formulation.

VI. Conclusion

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl- (CAS Reg. No. 23328-53-2) when used as an inert ingredient (UV stabilizer) at a maximum concentration of 10% in pesticide formulations applied to growing crops.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 16, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.920 revise the inert ingredient, phenol, 2-(2H-benzotriazole-2-yl)-6-dodecyl-4-methyl- (CAS Reg. No. 23328-53-2) in the table to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* *
Phenol, 2-(2H-benzotriazol-2-yl)-6-dodecyl-4-methyl-, (CAS Reg. No. 23328-53-2)	Not more than 10% by weight of pesticide formulations	UV stabilizer
* * *	* *	* *

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